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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,300	09/26/2003	Xiang-Yang Han	UTXC:766US	8195

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EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,300

Applicant(s)

HAN ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-28 and 31-46 are drawn to a kit and a method for detecting the presence of an invasive mold in a subject comprising SEQ ID NO:1, classified in class 435, subclass 7.31.
 - II. Claims 1-26, 28-29 and 31-46 are drawn to a kit and a method for detecting the presence of an invasive mold in a subject comprising SEQ ID NO:5, classified in class 435, subclass 7.31.
 - III. Claims 1-26, 28 and 30-46 are drawn to a kit and a method for detecting the presence of an invasive mold in a subject comprising SEQ ID NO:6, classified in class 435, subclass 7.31.

The inventions are distinct, each from the other because of the following reasons:

(a) Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The groups are drawn to a plurality of disclosed patentably distinct nucleic acid sequences comprising materially different nucleic acids as evidence by separate SEQ ID Numbers provided within the specification. The separate nucleic acid sequences bear distinct structural or biochemical properties. For instance, SEQ ID NO:1 has 596 nucleic acids, SEQ ID NO:5 has 552 nucleic acids and SEQ ID NO:6 has 495 nucleic acids. Therefore, each disclosed patentably distinct nucleic acid sequence is

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considered a separate invention. The instant specification does not disclose that these sequences would be used together. The methods of detection as defined by groups I-III are unrelated as they utilize different nucleic acid sequences, which demonstrates that each method has a different function and mode of operation. Each invention performs its function using a structurally and functionally divergent material, such as SEQ ID NO:1, 5 or 6. The groups are directed to different molecules which are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each group comprises separate and distinct nucleic acid sequences that do not share a substantial structural feature disclosed as being essential to the utility of the invention. Therefore, each method is unrelated. For these reasons the Inventions I-III are patentably distinct.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing which inventions are obvious variants of each other or clearly admit on the record which inventions are obvious variants of each other. If the inventions are deemed obvious variants of each other, then if the examiner finds one of the inventions unpatentable over the prior art, the evidence submitted by applicant or admission of record by applicant may be used in a rejection under 35 U.S.C. §103(a) of the other inventions.

Furthermore, the distinct nucleic acid sequences require separate and distinct searches. In the instant case, the search of the methods and sequences are not

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coextensive. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also found within the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to a particular nucleic acid sequence which would not have described the other sequences. Searching, therefore is not coextensive. In addition, the claims include sequences whose search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. As such, it would be burdensome to search the inventions of groups I-III together.

3. Because these inventions are distinct for the reasons given above, and have acquired a separate status in the art as shown by their different classification, the search required for each group is not required for the other groups since each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Species Election

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I: *Aspergillus* species, *Fusarium* species or *Scedosporium* species.

Aspergillus species are a genus of mitosporic fungi containing about 100 species and

eleven different teleomorphs in the Trichocomaceae family. *Fusarium* species are in the mitosporic Hypocreales fungal genus comprised of various species that are important parasitic pathogens of plants and a variety of vertebrates wherein teleomorphs include Gibberella. *Scedosporium* species belong to the mitosporic fungal genus previously called Monosporium and these teleomorphs include pseudallescheria. Thus the *Aspergillus*, *Fusarium* and *Scedosporium* species are structurally distinct fungi. And these fungi as determined by their different structure and associated functions are patentably distinct, each from the other. And one fungus is not required to practice the invention with another. Each fungi comprises separate and distinct functions that do not share a substantial structural feature disclosed as being essential to the utility of the invention.

Thus it is noted that if applicant elects *Aspergillus* species claims 18-20 will be examined. If applicant elects *Fusarium* species claims 18, and 21-22 will be examined. If applicant elects *Scedosporium* species, claims 18 and 23-24 will be examined.

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-17 and 21-46 are generic.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
August 4, 2005

